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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MEDTRONIC, INC.
710 MEDTRONIC PARK
MINNEAPOLIS, MN 55432-9924

EXAMINER

ROBERTS, DARIN

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/692,990

Applicant(s)

DENO ET AL.

Examiner

Darin R. Roberts

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 20-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17-19 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-6, 9, 10, 12, 13, 15, 16, 20-24, 27-29, 31, 33, 35, 37, 38, 42, 43, 46, 49 and 52 is/are rejected.
- 7) ☒ Claim(s) 3, 4, 7, 8, 11, 14, 17, 25, 26, 30, 32, 34, 36, 41, 45, 47, 48, 50, 51 and 53-56 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/14/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered ***claims 25-52*** have been renumbered 26-56 respectively.

Claim 1 is objected to because of the following informalities: the word "extra" appears to be repeated in the last line of ***claim 1***. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 recites the limitation "the table" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 5, 6, 9, 10, 12, 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Burnes et al. (US 2004/0220640 A1).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the

inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

In reference to **claims 1, 10, 12**, the Burnes et al. publication teaches a method of delivering and withholding extra-systolic stimulation through blanking (see pp. [0077] & pp. [0078] as well as sensing electrical activity of the heart (pp. [0043] & pp. [0046]) and correlating the head rate signal and an extra-systolic interval for an extra-systolic stimulation therapy to a data set having at least a plurality of head rates and a plurality of extra-systolic intervals (see pp. [0011] & pp. [0078] & pp. [0065]).

In reference to **claims 2, 5, 6**, Burnes et al. teaches the use of a “ ‘look-up’ table of ESI’s is compiled by generating a family of electrical restitution curves or electrical restitution measurement parameters for varying heart rates ... During ESS therapy delivery, the ESI is adjusted according to ‘look-up’ table values as heart rate or pacing rate varies (see pp. [0016]).

In to reference to **claim 9**, Burnes et al. teaches that a “portion of the memory 226 may be configured as a number of recirculating buffers capable of holding a series of measured R-R or P-P intervals for analysis by the microprocessor 224 for predicting or diagnosing an arrhythmia” (see pp. [0063])

Claims 1, 15, 16, 20, & 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Mulligan et al. (US 6438408 B1).

In reference to **claim 1**, the Mulligan patent teaches a method for one of delivering and withholding delivery of an extra-systolic stimulation cardiac pacing

therapy through blanking (see column 15, lines 31-35), as well as sensing electrical activity of a heart via EMG sensors. Mulligan also teaches correlating the heart rate signal and an extra-systolic interval for an extra-systolic stimulation therapy to a data set having at least a plurality of heart rates and a plurality of extra-systolic intervals (see column 6, lead lines 56-67) based on the correlation either delivering or inhibiting delivery of the extra extra-systolic stimulation therapy (see column 15, lines 31-35).

In reference to **claim 15**, Mulligan teaches a method wherein at least a portion of the correlated data sets incorporate information regarding a diastolic compromise condition (see column 18, lead lines 27-37).

In reference to **claim 16**, the Mulligan patent teaches A method according to wherein for a plurality of relatively low heart rates: delivering the extra-systolic stimulation therapy for every cardiac cycle, and for a plurality of relatively high heart rates: withholding delivery of the extra-systolic stimulation therapy (see column 6, lead lines 44-55)

In reference to **claim 20**, Mulligan teaches a method for determining whether to deliver or withhold delivery of an extra-systolic stimulation cardiac pacing therapy, comprising of sensing electrical activity of a heart to provide a heart rate signal for said heart (see column 6, lines 9-20) obtaining a stored value of an extra-systolic stimulation pulse amplitude or a extra-systolic stimulation pulse duration for a ventricular-coupled extra-systolic stimulation therapy (see column 6, lines 56-66, mapping the heart rate signal to a table containing at least a plurality of head rates and a plurality of extra-systolic intervals; and based on

the mapped location on the table delivering, or inhibiting delivery of, the extra extra-systolic stimulation therapy (see column 4, lines 3-13 & lines 59-67).

In reference to **claim 21**, Mulligan teaches a method storing information related to a reduced risk of tachycardia induction for a plurality of relatively high heart rates or a plurality of relatively short extra-systolic intervals based at least in part upon either the extra-systolic stimulation pulse amplitude or the extra-systolic stimulation pulse duration. Mulligan also teaches the use of an IMD which is programmed to continuously monitor the heart. Such an IMD would inherently possess a table or template of some sort to refer to when determining if stimulation should be provided (see column 21, lines 32-43).

Claims 22, 23, 24, 37, 38, 39, 40, 42-44, 46, 49, & 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Burnes et al. (US 2004/0220631 A1). The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C.

102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

In reference to **claim 22**, Burnes et al. teaches a method for initiating or gradually suspending delivery of an extra-systolic stimulation cardiac pacing therapy (see pp. [0067] & pp. [0102]), comprising of sensing electrical activity of a heart to provide a heart rate signal for said heart, correlating the heart rate signal and an extra-systolic interval for an extra-systolic stimulation therapy to a therapy initiation and suspension table containing at least a plurality of heart rates and a plurality of extra-systolic intervals based on the mapped location of the heart rate signal on the table and the mapped extra-systolic interval either delivering, or inhibiting delivery of, the extra extra-systolic stimulation therapy, wherein the therapy initiation-and-suspension (see pp. [0007] & pp. [0011] & pp. [0119]). Burnes et al. also includes a plurality of therapy transition rules, wherein one therapy transition rule provides a series of relatively long extra-systolic intervals compared to a cardiac cycle interval for a short period of time following initial delivery of the extra-systolic stimulation therapy and wherein said intervals are progressively shortened as the heart rate decreases during delivery of the extra-systolic stimulation therapy, or wherein delivery of the extra-systolic stimulation therapy may not be suspended immediately in the event that the

heart rate exceeds a pre-established heart rate limit (see pp. [0003], & pp. [0077] & pp. [0088]).

In reference to **claim 23**, Burnes et al. teaches a method according to claim 22, wherein the table includes empiric head rate-based rules for refractory period changes of a chamber of the head for a plurality of heart rates (see pp. [0014]).

In reference to **claim 24**, Burnes et al. teaches a method wherein the table includes evoked response information, said information derived from measurements of an evoked response from the extra-systolic stimulation therapy, said information establishing, for at least one cardiac cycle, a refractory period of the chamber of the head (see pp. [0014] & [0015]).

In reference to **claim 37** (formerly 36), the Burnes et al. publication teaches a method of extra-systolic therapy delivery to a patient suffering from head failure, comprising of substantially continuously delivering an extra-systolic stimulation therapy to at least one cardiac chamber of a head failure patient (see pp. [0009] & pp. [0010]).

In reference to **claim 38** (formerly 37), Burnes et al. teaches withholding the delivery of extra-systolic stimulation via blanking (see pp. [0067]) as well as a means for sensing electrical activity of a heart to provide a heart rate signal of said heart (see pp. [0063]). Burnes also teaches a means for correlating the heart rate signal and an extra-systolic interval for an extra-systolic stimulation therapy to a data set having at least a plurality of heart rates and a plurality of

extra-systolic intervals, and based on the correlation either delivering or inhibiting delivery of the extra-systolic stimulation therapy.

In reference to **claim 39** (formerly 37), the use of a data set that includes empiric heart-rate data as guidance refractory period changes of a chamber of the heart for a plurality of heart rates (see pp. [0049] & pp. [0119]). The examiner is assuming that the

In reference to **claim 40**, (formerly claim 38) Burnes et al. teaches a wherein the data set includes evoked response information, said information derived from measurements of an evoked response from the extra-systolic stimulation therapy, said information establishing, for at least one cardiac cycle, a refractory period of the chamber of the head (see pp. [0014] & pp. [0015]).

In reference to **claims 42 & 43** (formerly 40 & 41 respectively) the Burnes et al. publication teaches system wherein at least some of said plurality of correlated heart rates and extra-systolic intervals incorporate reduced extra-systolic intervals for a set of relatively higher head rates (see pp. [0017]).

In reference to **claim 44** (formerly claim 42), Burnes et al. teaches supplying extra-systolic stimulation at a safe interval, which can be referred to as a security-timing margin, for heart rates and extrasystolic intervals (see pp. [0115] & pp. [0119]).

In reference to **claim 46** (formerly 44), Burnes et al. teaches a system according to claim wherein at least some of the correlated data sets incorporate information regarding arrhythmia detection (see pp. [0060]).

In reference to **claim 49** (formerly 45), the Burnes et al. publication teaches a blanking period that changes in length according to the recovery time of the user following a extra systolic stimulation (see pp. [0101] & pp. [0102]).

In reference to **claim 52** (formerly 49), the Burnes device possesses arrhythmia detection capabilities (see pp. [0061]), thus the Burnes device must inherently possess information regarding arrhythmic behavior. Because diastolic compromise can be classified under arrhythmic behavior, thus one can conclude that the Burnes device possesses information regarding diastolic compromise.

In reference to **claim 27** (formerly claim 26), the Burnes publication teaches a programmable processor that delivers or withholding delivery of an extra-systolic stimulation therapy (see pp. [0067] & pp. [0102]), comprising of instructions for sensing electrical activity of a head to provide a heart rate signal for said head (see pp. [0011]), instructions for mapping the head rate signal and an extra-systolic interval for an extra-systolic stimulation therapy containing at least a plurality of head rates and a plurality of extra-systolic intervals; and based on the location on the table of the mapped head rate signal and the mapped extra-systolic interval either instructions for delivering, or inhibiting delivery of, the extra extra-systolic stimulation therapy (see pp. [0106] - pp. [0108]). The Burnes publication, on the other hand, does not teach placing the mapping methods onto a computer readable medium. The Burnes publication also teaches placing device instructions onto a computer readable medium (see claim 21).

In reference to **claim 28** (formerly claim 27), Burnes et al. teaches the use of a device wherein a table stored within the device includes empiric heart rate-

based rules for a refractory period changes of a chamber of the heart for a plurality of heart rates (see pp. [0015] & pp. [0119]). The Burnes publication also teaches placing device instructions onto a computer readable medium (see claim 21).

In reference to **claim 29** (formerly claim 28) the Burnes et al. patent teaches a device possessing a table wherein the table includes evoked response information, said information derived from measurements of an evoked response from the extra-systolic stimulation therapy, said information establishing, for at least one cardiac cycle, a refractory period of the chamber of the heart (see pp. [0015] & pp. [0119]). The Burnes publication also teaches placing device instructions onto a computer readable medium (see claim 21).

In reference to **claim 31** (formerly claim 30), the Burnes publication teaches device wherein said device possesses a table possessing at least some of said plurality of mapped heart rates and extra-systolic intervals incorporate reduced extra- systolic intervals in the event that the heart rate increases (see pp. [0108]). The Burnes publication also teaches placing device instructions onto a computer readable medium (see claim 21).

In reference to **claim 32** (formerly claim 31), the Burnes publication teaches a device which a device some of said plurality of mapped heart rates and extra-systolic intervals incorporate reduced extra-systolic intervals in the event that the head rate increases (see pp. [0077] & pp. [0078]). The Burnes publication also teaches placing device instructions onto a computer readable medium (see claim 21).

In reference to **claim 33** (formerly claim 32) the Burnes publication teaches a device wherein said mapped heart rates of the device and extra-systolic intervals incorporate a safety interval that can be described as a security-timing margin for a tachycardia induction portion of the table (see pp. [0014]). The Burnes publication also teaches placing device instructions onto a computer readable medium (see claim 21).

In reference to **claim 35** (formerly 34) the Burnes publication teaches mapped locations of a table that incorporate information regarding enhanced arrhythmia detection (see pp. [0119]). The Burnes publication also teaches placing device instructions onto a computer readable medium (see claim 21).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of

35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 27 & 28 are rejected under 35 U.S.C. 103(a) as being obvious over Burnes et al. (US 2004/0220631).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claims 27 & 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulligan et al. (US 6438408 B1).

In reference to **claim 27** (formerly claim 26), the Mulligan et al. patent teaches the use of signal processing circuitry, which can cause a programmable processor to perform a method of delivering or withholding delivery of an extra-systolic stimulation therapy comprising instructions for sensing electrical activity of a heart to provide a heart rate signal for said heart (see column 3, lead lines 19-27). The Mulligan patent teaches providing extrasystolic pulses after and extra systolic interval has occurred thus the Mulligan device must inherently possess saved (or mapped) heart rates and extra systolic intervals for an extra-systolic stimulation therapy to a table or template (see column 6, lead lines 56-66) containing at least a plurality of heart rates and a plurality of extra-systolic intervals; and based on the location on the table of the saved (or mapped) heart rate signal and the mapped extra-systolic interval either instructions for delivering, or inhibiting delivery of, the extra extra-systolic stimulation therapy (see column 3, lead lines 19-27). The Mulligan et al. patent, on the other hand, does not explicitly teach placing the mapping methods onto a computer readable medium.

However it would have been obvious to one of ordinary skill in the art to place the aforementioned aspects of the Mulligan et al. patent onto a computer readable medium to provide a convenient means for altering stimulation parameters and/or to transfer data from one device to another.

In reference to **claim 28** (formerly claim 27), Mulligan et al. teaches the use of a device wherein a table stored within the device includes empiric heart rate-based rules for a refractory period changes of a chamber of the heart for a

plurality of heart rates (see column 18, lead lines 51-61 & column 21, lines 53-61).

The Mulligan et al. patent, on the other hand, does not teach placing the mapping methods onto a computer readable medium.

However it would have been obvious to one of ordinary skill in the art to place the aforementioned aspects of the Mulligan et al. patent onto a computer readable medium to provide a convenient means for altering stimulation parameters and/or to transfer data from one device to another.

Allowable Subject Matter

Claims 3, 4, 7, 8, 11, 14, 25, 26, 30, 32, 34, 36, 41, 45, 47, 48, 50, 51, & 53-56 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 17-19 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darin R. Roberts whose telephone number is (571)272-5558. The examiner can normally be reached on 7:30am to 4:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The

fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Darin Roberts
Patent Examiner
Art Unit 3762

D. R.



JEFFREY R. JASTRZAB
PRIMARY EXAMINER
4/7/06